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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,808	10/16/2000	Ib Mendel-Hartvig		2872

7590 04/09/2002

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EXAMINER
COUNTS, GARY W

ART UNIT	PAPER NUMBER
1641	8

DATE MAILED: 04/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/582,808	Applicant(s) MENDEL-HARTVIG ET AL.	
	Examiner Gary W. Counts	Art Unit 1641	

-- The MAILING DATE of this communication app ars on th cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 1 "associated with" is vague. It is unclear what applicant intends.

Claim 1, line 5 "Reactant* " is vague and indefinite. It is unclear what "*" represents. Does it represent a label or marker, or does it represent some other biospecific affinity reactant? See deficiencies throughout the claims.

Claim 1, line 6 "firmly anchored" is vague. It is unclear what is considered to be firmly anchored. Does it mean that the reactant never comes off or does it mean that the bond has a strength that will allow for the reactant to withstand a certain amount of force. See deficiencies throughout the claims.

Claim 1, line 9 "being related to" is vague. It is unclear what relationship applicant is referring to.

Claim 4 the recitation "capable of" is vague and indefinite. Can the capturer bind a biospecific affinity reactant or not? See also deficiency found in claim 21.

Claim 4 the recitation "via" is vague and indefinite. It is unclear what the term encompasses. See also deficiency found in claims 21 and 30.

Claim 4 the recitation "biospecific affinity a reactant" is vague. It is unclear what applicant intends. Does applicant intend a biospecific affinity reactant or something else? See also deficiency found in claim 21.

Claim 4, the recitation "a reactant" is vague and confusing. Is this the same as Reactant* or is it the same as the bioaffinity specific reactant of claim 1 or is it another reactant?

Claim 8, line 2 "the label particles" there is insufficient antecedent basis for this limitation.

Claim 13, line 3 "the ternary complex" there is insufficient antecedent basis for this limitation. See also deficiency found in claim 30.

Claim 13, line 4 "Reactant' " is vague and indefinite. It is unclear what " ' " represents. See deficiencies found throughout the claims.

Claim 13, line 4 "are able to" is vague and indefinite. Does Reactant' and Reactant* simultaneously bind analyte biospecifically or not? See also deficiency found in claim 30.

Claim 14 the recitation "antigen/hapten" is vague. Does it mean that it is an antigen-hapten complex or does it mean that it is an antigen or a hapten?

Claim 38, line 2 "the sample application site" there is insufficient antecedent basis for this limitation.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

6. Claims 1-5, 7, 8, 10-13, 15, 18-22, 24, 25, 27-30, 32 and 35-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Charlton et al (US Patent 5,714,389).

Charlton et al disclose an immunoassay method for determining the presence of a ligand (analyte) in a sample. Charlton et al disclose applying a sample to an inlet of a test device which comprises a sorbent material which defines a lateral flow path, capable of transporting an aqueous solution by capillary action to a test site (detection zone). Charlton et al disclose that a conjugate comprising a protein bound to a colored

particle (Reactant*) is mixed with the sample and inserted into the test device. Charlton et al also disclose that the conjugate may be predeposited in the test strip upstream of the test site (detection zone). Charlton et al disclose that the conjugate and sample flows to the test site (detection zone) which comprises latex particles entrapped or fixed in the flow path having an immobilized protein (antibody)(capturer) on their surface. Charlton et al disclose that if the analyte is present it reacts with immobilized binding protein (antibody) at the test site and forms a sandwich comprising immobilized binding protein-ligand binding protein colored particle (Reactant*) (col 3, line 21 – col 4, line 67). Charlton et al disclose that the latex beads entrapped in the test site have a size of 0.3 microns (col 7, lines 61-64). Charlton et al disclose that the color particles have a size of 18 nm (0.018 um) (col 8, lines 16-18). Charlton et al also disclose packing the components into a test kit (col 4, line 17).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 6, 9, 23, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton et al (US Patent 5,714,389) in view of Brown et al (US Patent 5,149,622).

See above for teachings of Charlton et al.

Charlton et al differ from the instant invention in failing to teach the particles anchoring the capturer have a size which is smaller than a smallest inner dimension of the flow channels of the matrix.

Brown et al disclose a flow device in which particles having a substance capable of reaction with the analyte in the sample, are immobilized in a matrix. Brown et al disclose that the average diameter of the particles is less than the average pore size of the matrix (see abstract). Brown et al disclose that by having the particle sizes having a size which is smaller that the flow channels of the matrix allows for an improved solid-phase analytical device and a binding assay which is highly advantageous over devices and assay methods of the prior art.

It would have been obvious to one of ordinary skill in the art to incorporate particles which have a smaller diameter than that of the matrix as taught by Brown et al into the method of Charlton et al because Brown et al shows that by having the particle sizes having a size which is smaller that the flow channels of the matrix allows for an improved solid-phase analytical device and a binding assay which is highly advantageous over devices and assay methods of the prior art.

With respect to the flow channels having a smallest inner dimension in the range of 0.4-1000 um as recited in the instant claims, the optimum dimension of the flow channels can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is

not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation ." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

9. Claims 14, 16, 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton et al in view of Devlin et al.

See above for teachings of Charlton et al.

Charlton et al differ from the instant invention in failing to teach the analyte is of IgE class directed to an allergen.

Devlin et al disclose that sandwich techniques can also be used to assay antibodies rather than antigens. Devlin et al also disclose determination of an antigen specific IgE by immobilizing antigens to solid phases. The antigens are biospecific for the corresponding antibody. Devlin et al disclose that these IgE antibodies are directed to an allergen (col 2, line 57 – col 3, line 1). Devlin et al disclose that this immunoassay allows for the measurement of antigenic substances in biological materials such as serum, plasma and whole blood and also allows for the determination of an allergen.

It would have been obvious to one of ordinary skill in the art to incorporate the use of immobilized antigens as taught by Devlin et al into the method of Charlton et al because Devlin et al shows that this allows for the detection of IgE and also allows for the measurement of

antigenic substances in biological materials such as serum, plasma and whole blood and also allows for the determination of an allergen.

10. Claim 17 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton et al in view of Self et al (US Patent 4,446,231).

See above for teachings of Charlton et al.

Charlton et al differ from the instant invention in failing to teach the diagnosis of an autoimmune disease.

Self et al disclose that immunoassays are used for the detection and/or determination of autoimmune diseases. Self et a disclose shows that immunoassays have a wide application, in both clinical and non-clinical fields and that they are particularly useful in any circumstance where it is necessary to detect and/or determine small or very small amounts of substances.

It would have been obvious to one of ordinary skill in the art to use immunoassays as taught by Self et al for the diagnosis of autoimmune diseases because Self et al that immunoassays are used for the detection and/or determination of autoimmune diseases and that immunoassays have a wide application, in both clinical and non-clinical fields and that they are particularly useful in any circumstance where it is necessary to detect and/or determine small or very small amounts of substances.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary W. Counts
Examiner
Art Unit 1641
April 8, 2002

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SUPERVISORY PATENT EXAMINER
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04/08/02